Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-48 are pending in the application, with claim 1 being the independent claim. Claims 46-48 are listed with the status identifier "withdrawn" solely to comply with the requirements of 37 C.F.R. § 1.142, since the restriction requirement is traversed.

II. The Amendments

Claim 8 has been amended to recite compounds comprising one or more CD1d/β2-microglobulin complexes linked to an antibody or fragments thereof, wherein the antibody fragment thereof is a scFv fragment. Support for this amendment can be found at page 19, paragraph [0054]; page 20, paragraph [0056]; and page 70, paragraph [0210] in the disclosure. Accordingly, no new matter is believed to have been added by this amendment and its entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objection and rejections and that they be withdrawn.

III. The Requirement for Unity of Invention and Election of Species Under 35 U.S.C. §§ 372 and 121.

In reply to the Office Action dated **January 21, 2009**, Applicants hereby provisionally elect to prosecute the claims of Group **I**, represented by claims 1-45. This

election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

The election is made **with traverse.**

Applicants assert that this Restriction Requirement based on lack of unity of invention is unfounded. According to 37 C.F.R. § 1.475(a), "a national stage application shall relate to one invention only *or to a group of inventions so linked as to form a single general inventive concept.*" *Id.* (emphasis added). The Manual of Patent Examining Procedure (M.P.E.P.) provides the following guidance regarding "a single general inventive concept":

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

M.P.E.P. § 1893.03(d) (Rev. 6, Aug 2007) at 1800-208; *see also*, 37 C.F.R. § 1.475(a).

The Examiner asserts that the claims of Groups **I-II** do not share a corresponding special technical feature as the technical feature of a "CD1d complex linked to an antibody or fragment thereof... does not make a contribution over the prior art as evidenced by US 2002/0071842 A1 (IDS reference) in view of WO 01/78768 A2 (IDS reference)." (Office Action at page 2). Applicants respectfully disagree.

In the present case, a corresponding special technical feature that is common to Groups **I-II** is the use of compounds comprising CD1d/β2-microbulin complexes linked to an antibody or fragment thereof specific for cell surface markers. This feature is present in all of the pending claims, and therefore links the claims as a single general

inventive concept under PCT Rule 13.1. As such, the claims in Groups **I-II** should be grouped and examined together.

The Examiner accurately states that the U.S. Pat. Appl. publication U.S. 2002/0071842 A1 does not teach CD1d/β2-microglobulin-antibody compounds of the present invention that specifically target cells expressing cell surface markers. (Office Action at page 3). Rather, this reference merely discusses CD1d fusion polypeptides used to screen and identify CD1-restricted T cells and novel CD1 antigens. Therefore, the present invention makes a contribution over the cited reference in that it offers a targeting mechanism to draw CD1d-restricted NKT cells to target cells in order to effect an innate immune response.

PCT publication WO 01/78768 A2 also does not teach CD1d/β2-microglobulin-antibody compounds of the present invention that specifically target cells expressing a cell surface markers. This reference generally discusses the use of MHC-peptide molecules that are conjugated to antibodies to target antigen-specific immune responses. While CD1d shares structural similarities to MHC Class 1 molecules, the gene(s) encoding CD1d are actually located on an entirely different locus, distinguishing CD1d from MHC molecules. Additionally, the reference does not teach the use of CD1d molecules, molecules associated with glycolipid antigens, or targeting an innate immune response to a cell expressing a cell surface marker. As such, the present invention makes a contribution over the cited reference in that it offers a targeting mechanism to draw CD1d-restricted NKT cells to target cells in order to effect an innate immune response.

As neither cited reference, alone or combined, teaches ***CD1d/β2-microglobulin-antibody compounds that specifically target cells expressing a cell surface markers***,

Applicants respectfully submit that the references do not disclose the corresponding special technical feature common to Groups **I-II** of the instant application. Accordingly, the claims of Groups **I-II** should be grouped and examined together.

If the Examiner maintains the restriction requirement between Groups **I** and Group **II**, Applicants note that in light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996), and the Official Gazette Notice 1184 OG 86 (March 26, 1996), the Examiner is required to rejoin claims 46-48 (Group **II**) if the claims of Group **I** are found to be allowable. Specifically, the OG Notice states that

> in the case of an elected product claim, *rejoinder will be permitted when a product claim is found allowable* and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

1184 OG 86 (March 26, 1996) (emphasis added). Accordingly, if the claims of elected Group **I** are found to be allowable, Applicants respectfully request that the claims of Group **II** be rejoined and examined for patentability for the reasons discussed above.

Additionally, the Examiner has indicated that, upon election of Group **I,** further elections of species within the restricted Group are also required. (Office Action at page 4). The Examiner has required Applicants to elect a single species of CD1d/β2-microglobulin complexes (with or without an antigen). Applicants hereby elect to prosecute CD1d/β2-microglobulin complexes with antigen molecules. Elected claims 1 and 7-45 read on this elected species.

The Examiner has required Applicants to elect a single species of antigen binding molecule. Applicants hereby elect to prosecute scFv fragments. Elected claims 1-6, 8, 10-35, and 44-45 read on this elected species.

The Examiner has required Applicants to elect a single species of cell surface marker. Applicants hereby elect to prosecute Her2/neu. Elected claims 1-11 and 36-45 read on this elected species.

The Examiner has required Applicants to elect a single species of attachment methods by which the CD1d/β2-microglobulin complexes are attached to antibodies or fragments thereof. Applicants hereby elect to prosecute attachments methods that require the CD1d/β2-microglobulin complexes to be fused to antibodies or fragments thereof. Elected claims 1-40 and 44-45 read on this elected species.

Finally, the Examiner has required Applicants to elect a single species of CD1d/β2-microglobulin complexes (with or without costimulatory molecules). Applicants hereby elect to prosecute CD1d/β2-microglobulin complexes without costimulatory molecules. Elected claims 1-43 and 46-45 read on this elected species.

These elections are made without prejudice to or disclaimer of the other claims or inventions disclosed. These elections are made without traverse.

Additionally, in accordance with 37 C.F.R. § 1.141(a), with respect to the species elections made, Applicants reserve the right to claim additional species, and/or to have

additional species searched and/or examined, in the event that a generic claim is found to be allowable.

Reconsideration and withdrawal of the restriction and election of species requirements, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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